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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,626	04/11/2001	R. G.F. Visser	294-52 CIP	1804
23869	7590 08/27/2002			
	N & BARON, LLP		EXAMINER	
6900 JERICHO TURNPIKE SYOSSET, NY 11791			MCINTOSH III, TRAVISS C	
		_	ART UNIT	PAPER NUMBER
			1621	
			DATE MAILED: 08/27/2002	6

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

			File Cop	y				
•		Application No.	Applicant(s)	<del> </del>				
Office Action Summary		09/832,626	VISSER ET A	L.				
		Examiner	Art Unit					
		Traviss C McInto						
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
THE I - Exter after - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. In period for reply specified above is less than thirty (30) days, a repropersion of the propersion of	136(a). In no event, how ly within the statutory mi will apply and will expire e, cause the application t	ever, may a reply be timely filed  nimum of thirty (30) days will be considered  SIX (6) MONTHS from the mailing date of the opening of the come ABANDONED (35 U.S.C. § 133)	his communication.				
1)🖂	Responsive to communication(s) filed on 26	<i>July 2002</i> .						
2a)[_	This action is FINAL. 2b)⊠ TI	his action is non-f	inal.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims								
· _	Claim(s) 1-21 is/are pending in the applicatio	n						
•	4a) Of the above claim(s) <u>1-15</u> is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.								
6)⊠ Claim(s) <u>16-21</u> is/are rejected.								
7) Claim(s) is/are objected to.								
· ·	8) Claim(s) 1-21 are subject to restriction and/or election requirement.							
Application Papers								
9) 🗌 -	The specification is objected to by the Examine	er.						
10)⊠ The drawing(s) filed on <u>11 April 2001</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.								
12)☐ The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. §§ 119 and 120								
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a) ☐ All b) ☐ Some * c) ⊠ None of:								
	1.⊠ Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
	<u> </u>							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).								
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>								
Attachment								
2) 🔲 Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) _	4) 5) 6)	Interview Summary (PTO-413) Paper Notice of Informal Patent Application Other:					
S. Patent and Tra		ction Summary	D.	art of Paner No. 6				

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#### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C 121:

- I. Claims 1-7, drawn to a protoplast and a method of producing same classified in class 435, subclass 421.
- II. Claim 8-12, drawn to a transformed protoplast and method for producing same using protoplast of Group I classified in class 435, subclass 421.
- III. Claim 13-15, drawn to a plant and a method producing same using protoplasts of Group I or II classified in class 800, subclass 295.
- IV. Claims 16-18 drawn to a method of isolating starch from a plant of Group III classified in class 536, subclass 1.11.
- V. Claims 19-21 drawn to a starch obtained by the method of Group IV classified in class 536, subclass 1.11.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as another protoplast produced by different means. There is nothing indicating that the methods of producing the protoplast of Group I are critical in protoplast produced and subsequently used in the method of transformation of protoplasts as in

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Group II, therefore any protoplast can be used in the transformation method of Group II to produce a transformed protoplast.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ... § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as the product as produced in Group I or Group II.

Inventions I and IV are unrelated. In the instant case the different inventions are drawn to a protoplast and method of producing the same and to a method of isolating starch from a tuber of a plant. A search for one Group would not necessitate a search for the other and a reference rendering one group obvious would not necessarily render the other obvious. Applicant is not entitled to examination of multiple methods, as this indeed would impose undue burden upon the examiner in charge of the application.

Inventions I and V are unrelated. In the instant case the different inventions are drawn to a protoplast and a method of producing the same and to a starch. A search for one Group would not necessitate a search for the other and a reference rendering one group obvious would not necessarily render the other obvious. Applicant is not entitled to examination of multiple compounds, as this indeed would impose undue burden upon the examiner in charge of the application.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

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product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as the product as produced in Group I or Group II.

Inventions II and IV are unrelated. In the instant case the different inventions are drawn to a transformed protoplast and method of producing the same and to a method of isolating starch from a tuber of a plant. A search for one Group would not necessitate a search for the other and a reference rendering one group obvious would not necessarily render the other obvious. Applicant is not entitled to examination of multiple methods, as this indeed would impose undue burden upon the examiner in charge of the application.

Inventions II and V are unrelated. In the instant case the different inventions are drawn to a transformed protoplast and a method of producing the same and to a starch. A search for one Group would not necessitate a search for the other and a reference rendering one group obvious would not necessarily render the other obvious. Applicant is not entitled to examination of multiple compounds, as this indeed would impose undue burden upon the examiner in charge of the application.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as another plant. The plant used in the starch

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isolation steps of Group IV can be one derived from natural means, or wherein a transformed protoplast has been induced to produce a plant.

Inventions III and V are unrelated. In the instant case the different inventions are drawn to a plant and a method producing same and to a starch. A search for one Group would not necessitate a search for the other and a reference rendering one group obvious would not necessarily render the other obvious. Applicant is not entitled to examination of multiple compounds, as this indeed would impose undue burden upon the examiner in charge of the application.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as the process as disclosed by Verberne et al. (US Patent 3,890,888).

Should applicant elect the invention of Group IV, applicant is entitled to examination of Group V. The compound of Group V and one method of making will be examined in the instant application 09/832,626.

Because these inventions are distinct for the reasons given above and the search required for an individual Group is not required for the remaining Groups, restriction for examination purposes as indicated is proper. It would indeed impose an undue burden upon the examiner in charge of this application if the instant restriction is not advanced as set forth herein.

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During a telephone conversation with Attorney Susan Sipos on July 26, 2002 a provisional election was made with traverse to prosecute the invention of Group IV, claims 16-18. As noted supra, the Examiner in charge of this application will examine the claims of Group V with the provisionally elected invention of Group IV. Affirmation of this election must be made by applicant in replying to this Office action. Claim1-15 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

## **Priority**

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on May 20, 1996. It is noted, however, that applicant has not filed a certified copy of the 96201424.7 application as required by 35 U.S.C. 119(b).

It is noted that applicant claims benefit of copending Application No. 09/108,481, filed November 9, 1998. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable,

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within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

## Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

## Claim Objections

Claims 16-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). It is noted that claim 16 depends from non-elected claims, however it is the most

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method of isolating starch from a tuber plant comprising the steps of...". Additionally, please note that claim 18 has a spelling error where the claim recites "a vacuum filter followd by drying...". Appropriate correction is respectfully requested.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites, "followed by grating and milling it", clarity is required on what is meant to be encompassed by the recitation of "it".

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shieh et al. (WO 93/10255).

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The claims of the instant application are product by process claims wherein the applicant claims products drawn to a starch with at least a 95% purity level of amylopectin, made from a tuber of a plant.

Shieh et al. disclose a starch comprising at least about 90%, and more preferably 99% amylopectin (page 2, lines 18-23, and example 1 on page 9). Even though applicant claims a product by process, it is still anticipated by the prior art of Lane et al. *In re Thorpe, 227 USPQ 964, 966 (Fed Cir. 1985)*.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verberne et al. (US Patent 3,890,888) in view of Mitchell et al. (US Patent 4,285,735) and further in view of Tallberg et al. (US Patent 5,824,798).

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The claims of the instant invention are drawn to a method of isolating starch from a tuber plant comprising: washing the tuber followed by grating then milling, separating the starch from fibers and juice in a separator, sieving the starch, washing the starch in a hydrocyclone, and drying the starch in a vacuum filter followed by a drying tower.

Verberne et al. teaches of a method of recovering starch from root crops, such as cassava tubers and potatoes (column 1, lines 5-10) wherein the grating normally takes place at least twice (column 1, lines 27-28). The grated substance is then separated by means of hydrocyclones into juice mixed with fibers on one hand, and starch on the other. The starch fraction then undergoes filtration (sieving) and finally is purified by washing in a stream of fresh water in a second hydrocyclone (column 2, lines 51-62). What is not taught by Verberne et al. is to wash the tuber initially, to use a milling device, or to dry the product twice, however the Mitchell et al. patent addresses the use of a milling device and the Tallberg et al. patent addresses drying techniques for polysaccharide polymers isolated from tubers.

Mitchell et al. teach of a process for making a fructose polymer containing inulin from the dahlia tuber (abstract). Analogous to starch, which is a glucose polymer based polysaccharide, inulin is chiefly a fructose polymer based polysaccharide (column 1, lines 36-38). The process as taught by Mitchell et al. involves the isolation of a polysaccharide component by washing and scrubbing a tuber and grinding in any conventional hammer mill or grinder. The slurry produced is then filtered through a filter cloth to remove fibrous insolubles (column 2, lines 31-34 and column 3, lines 34-40) and the products are further derivitized as dictated by the patent. What Mitchell et al. do not teach is to use the washing and grinding steps as precursor steps in starch isolation from tubers.

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Tallberg et al. teach of a process for isolating amylopectin-type starch from a potato (column 1, lines 10-11). The process as taught by Tallberg et al. comprises, grating a potato, thereby releasing the starch from the cell wall, separating the fibers from the starch in centrifugal screens, then separating the starch from the juice in a hydrocyclone followed by a band-type vacuum filter. The product is then dried in two steps, first by pre-drying on a vacuum filter and subsequently by final drying in a hot air current (column 9, lines 21-35). What is not taught by Tallberg et al. is to wash the tuber followed by a milling step, or to wash the starch in the hydrocyclone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the washing and milling steps of Mitchell et al. as the precursor steps in Verberne et al's starch isolation procedure because Verberne et al. teach in the procedure to grate the tuber at least twice. One would be motivated to incorporate a milling technique in place of a grating step as it is known in the art that multiple gratings break the cell walls down to a size so small that the resulting fine fiber is not easily separated in the hydrocyclone or in sieving. One would be motivated to wash the tuber before use because one of ordinary skill in the art would recognize that there could be chemicals on the tuber if purchased from a supplier, or if a fresh tuber was picked from the earth, one would want to wash off any soil and residue from the tuber's outer surface to eliminate as many impurities as possible. Washing a tuber before use and incorporating a step that would allow for the cells to maintain a more stable size would be obvious to one of ordinary skill in this art.

It would have been obvious of one of ordinary skill in the art at the time the invention was made to incorporate the drying steps of Tallberg et al. into the process as taught by Verberne

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et al. in view of Mitchell et al. as noted above as these are just variations of standard drying techniques known in the industry. One would be motivated to incorporate these drying steps into the prior art process because these steps would allow for a crystallized product that could then be diluted to various levels based on the needs of the application.

The examiner notes there is no additional objective evidence currently of record in the instant application that indicates non-obviousness in view of the prior art cited supra.

#### Conclusion

Claims 1-15 withdrawn.

Claims 16-21 pending.

Claims 16-21 rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Johann R. Richter, Ph.D., Esq.
Supervisory Patent Examiner
Biotechnology and Organic Chemistry

Traviss C. McIntosh August 23, 2002

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